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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/612,929	04/30/96	HOLMES S	P50186-2

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EXAMINER	
HUFF,S	
ART UNIT	**PAPER NUMBER**
1642	19

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/612,929	Applicant(s) Holmes et al
	Examiner Sheela J. Huff	Group Art Unit 1642

☒ Responsive to communication(s) filed on *Apr 15, 1999* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-11, 14-18, and 30-39* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-11, 14-18, and 30-39* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 4/15/99 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/612929 is acceptable and a CPA has been established. An action on the CPA follows.

Double Patenting

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claims 1-11, 14-17, 30 and 32-38 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-2, 4-5, 7-21, 26-39 of US Patent No. 5914110. This is not a new rejection because this rejection was originally made when the made had not yet issued. The reasons for this rejection are of record in paper no. 10, mailed 5/9/97.

Applicant will address this rejection at time of allowance.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1 and 39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 10 of US Patent No. 5914110. This is not a new rejection because this rejection was originally made when the made had not yet issued. The reasons for this rejection are of record in paper no. 13 mailed 1/23/98.

Applicant will address this rejection at time of allowance.

Claim Rejections - 35 USC § 112

6. Claims 17-18 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The reasons for this rejection are of

record in paper no. 10, mailed 5/9/97. Please note: the only issue remaining in this rejection is the correlation of in vitro assays to in vivo use.

Applicant has not provided any new arguments to the remaining issue.

Claim Rejections - 35 USC § 102/103

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> or (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 32 remains rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ramanathan et al WO 91/09059 or JP-327725 or Chreiten et al J. Immunol. Methods vol. 117 p. 67 (1991). The reasons for this rejection are of record in paper no. 10, mailed 5/9/97.

Applicant argues that Harlow and Lane merely show a range of dissociation constants and do not provide any teaching as how to identify antibodies having a dissociation constant of equal to or less than 2×10^{-10}. Since Harlow and Lane do cite an average range for dissociation constants and since applicant's dissociation constant does fall within this range, it is inherent or reasonable that a portion of the reference antibodies have a dissociation constant of equal to or less than 2×10^{-10}. Applicant has not provided any objective evidence to rebut this.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 1 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Ramanathan et al WO 91/09059 or JP-327725 or Chreiten et al J. Immunol. Methods vol. 117 p. 67 (1991). The reasons for this rejection are of record in paper no. 10, mailed 5/9/97.

Applicant arguments with respect to Harlow and Lane have been addressed above.

12. Claims 1-2, 4, 14-17, 30-34 and 36 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Queen et al WO 90/07861 in view of Abrams et al US 5041381, Chreiten et al J. Immunol. Methods vol. 117 p. 67 (1991) and Curtis et al US 5108910. The reasons for this rejection are of record in paper no. 10, mailed 5/9/97.

Applicant argues that Queen et al does not remedy any of the deficiencies of the other references. Applicant has not address the combination of references or the motivation for combining the references.

13. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 91/09059 or Chreiten et al J. Immunol. Methods vol. 117 p. 67 (1991) in view of Oellerich, J. Clin. Chem. Clin. Biochem. vol. 22 p. 895 (1984).

Both primary references disclose screening procedures(ELISA) for anti-IL-4 antibodies (p. 16 of WO and p. 69 of Chreiten et al).

The only difference between the instant invention and the reference is that the IL-4 is not denatured.

As seen by Oellerich, various forms of ELISA are very well known in the art--these assays include assays in which the ligand to be detected is directly applied to the solid support of assays in which a capture antibody is used to capture the ligand (ie sandwich assay) which avoids the ligand being denatured.

Thus, in view of the well known immunoassays which include direct application of ligand or capture of the ligand with an antibody (sandwich assay), it would have been obvious to one of ordinary skill in the art at the time of the invention to use either of the known assays to screen for the anti-IL-4 antibodies.

Claim Rejections - 35 USC § 112

14. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 needs a correlation step correlating the excess IgE with the diagnosis.

15. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

The amendment to claim 5--56 to 58 is new matter. There appears to be no support for this change in the specification.

New Grounds of Rejection

16. Claims 1 and 18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 30-35 of U.S. Patent No. 5914110. Although the conflicting claims are not identical, they are not patentably distinct from each other because only difference between the two is the scope of the diseases to be treated.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5597710 and US 5705154 and US 5770403.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is (703) 305-7866. The Examiner can normally be reached on Monday, Wednesday and Thursday from 6:30am to 4:00pm.

If attempts to teach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Paula Hutzell, can be reached on (703)308-4310.

The FAX phone number for the group is (703)308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**paula.hutzell@uspto.gov**].

All Internet e-mail communications will be made of record in the application file. **PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122.** This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

Sheela J. Huff
June 24, 1999

Sheela J. Huff
Primary Examiner